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| EXAMINER | |
|---|---|
| SHABMAN, MARK A | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/517,382 | LARSEN ET AL. | |
| | Examiner | Art Unit | |
| | MARK SHABMAN | 2856 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *22-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/30/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**Claims 22-29 and 31-32** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanss US Patent 4,835,457 (hereinafter referred to as Hanss) in view of Graham US Patent 6,111,398 (hereinafter referred to as Graham).

Regarding **claims 22 and 23**, Hanss discloses an apparatus for the measurement of red blood cell deformity comprising two separate chambers 2a, 2b forming a housing, each comprising a cavity 11, 12. Cavity 11 (collection chamber) is separated by cavity 12 (mixing chamber) by a membrane 5 made of plastic material or polymer (column 2 line 37). The membrane contains an “orifice" in the pores which allow particles to pass through from one cavity to the other (column 2 line 38).

The description of the device further describes the electrodes 13, 14 as comprising a constant current through them as seen in figure 3. A change in voltage in the sensor characterizes the movement of the cells through the membrane. By spacing the electrodes apart in such a manner and keeping the current through them constant, the resulting electric field at the center of the orifice would be "homogenous” as claimed.

The interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within a range of 10μm

to 2000μm, or 30μm to 200μm for other applications (column 3 line 15). It would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham with the membrane of Hanss depending on the size of the particles passing through or if the cells under test were larger than those normally found in a human. Graham further describes the conduit 10 as a volumeter which measures the volume of liquid passing through. While Graham does not explicitly disclose using the volume meter to determine a period during which a fixed volume passes through the orifice, the volumeter is capable of measuring the volume passing through and thus would be capable of determining a period between a no volume passing through and a any desired amount passing through.

Regarding **claim 24**, Graham discloses the radius of the curvature of the rounded edges to be 1/2 the diameter of the orifice. As the Graham reference teaches towards rounding the orifice opening by a radius equal to one half of the diameter, it would have been obvious to one of ordinary skill in the art at the time of invention to change that amount to ¼ the diameter if desired to also improve the flow properties.

Regarding **claim 25**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be as low as 0.010mm (10μm). At a size of 10μm, in order for a particle or blood cell to pass through, roughness on the internal surface of the orifice could at a maximum be 5 μm before complete blockage could occur due to rough spots contacting one another which is within the range of 0-5μm claimed.

Regarding **claim 26**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within a range of 10μm to 2000μm, or 30μm to 200μm for other applications (column 3 line 15). Since the apparatus of Graham works on similar principles as that of Hanss by applying a current source both sides of a membrane to induce transmission of a particulate across the membrane, it would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham with the membrane of Hanss to allow for different sized particles to pass through.

Regarding **claim 27**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within a range of 10μm to 2000μm, or 30μm to 200μm for other applications (column 3 line 15). It would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham with the membrane of Hanss as these values are known in the art to be acceptable for the intended use of the invention.

Regarding **claim 28**, Graham notes in column 3 line 23 that a conduit wherein the length is equal to 3/4 of the diameter is acceptable and favorable for use. If the diameter is between 10μm to 2000μm as described in line 15 of the same column, then the length would fall in the range claimed.

Regarding **claim 29**, the apparatus of Hanss could be intended for “single use” if so desired by the user. It would have been obvious to one of ordinary skill in the art at the time of invention to create a sampling device in which the parts which were to come

in contact with a blood sample were disposable to help prevent the spread of any infectious diseases contained therein to the outside of the chambers.

Regarding **claim 31**, while there is no explicit indication of the "deviation of the orifice diameter along a longitudinal axis of the orifice" ranging from +/-1% to +/-10%, it would have been obvious to one of ordinary skill in the art at the time of invention to have manufactured the orifices as close to ideal as possible which be with as little deviation as possible, i.e. less than 10%.

Regarding **claim 32**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within a range of 10μm to 2000μm, (column 3 line 15). It would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham with the membrane of Hanss as these values are known in the art to be acceptable for the intended use of the invention and fall within the 10-50 μm range claimed.

Regarding **claims 33, 34 and 39**, Hanss discloses an apparatus for the measurement of red blood cell deformity comprising two separate chambers 2a, 2b forming a housing, each comprising a cavity 11, 12. Cavity 11 (collection chamber) is separated by cavity 12 (mixing chamber) by a membrane 5 made of plastic material or polymer (column 2 line 37). The membrane contains an “orifice" in the pores which allow particles to pass through from one cavity to the other (column 2 line 38).

The description of the device further describes the electrodes 13, 14 as comprising a constant current through them as seen in figure 3. A change in voltage in the sensor characterizes the movement of the cells through the membrane. By spacing

the electrodes apart in such a manner and keeping the current through them constant, the resulting electric field at the center of the orifice would be "homogenous" as claimed.

The interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within a range of 10μm to 2000μm, or 30μm to 200μm for other applications (column 3 line 15). It would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham with the membrane of Hanss depending on the size of the particles passing through or if the cells under test were larger than those normally found in a human. Graham further describes the conduit 10 as a volumeter which measures the volume of liquid passing through. As the claimed apparatus is an electrical impedance cell capable of supporting any number of particles suspended in a fluid, the limitation of "wherein a diameter of the particles is not greater than 60 percent of the diameter of the orifice" is deemed to be a limitation of the particles and not of the apparatus itself. As the apparatus of Hanss in view of Graham is capable of handling a liquid suspension with these limitations, it reads on the claim as written.

Regarding **claim 35**, Graham discloses the radius of the curvature of the rounded edges to be 1/2 the diameter of the orifice. As the Graham reference teaches towards rounding the orifice opening by a radius equal to one half of the diameter, it would have been obvious to one of ordinary skill in the art at the time of invention to change that amount to ¼ the diameter if desired to also improve the flow properties.

Regarding **claim 36**, the interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be as

low as 0.010mm (10μm). At a size of 10μm, in order for a particle or blood cell to pass through, roughness on the internal surface of the orifice could at a maximum be 5 μm before complete blockage could occur due to rough spots contacting one another which is within the range of 0-5μm claimed.

Regarding **claim 37**, the apparatus of Hanss could be intended for "single use" if so desired by the user. It would have been obvious to one of ordinary skill in the art at the time of invention to create a sampling device in which the parts which were to come in contact with a blood sample were disposable to help prevent the spread of any infectious diseases contained therein to the outside of the chambers.

Regarding **claim 38**, Hanss in view of Graham discloses the claimed invention with the exception of the bore in the outer surface of the housing and the sampling member. Berndtsson discloses a disposable sampling device for particle counting apparatus comprising a housing with a bore in the outer surface 55 (figure 2, page 5 line 29) allowing for liquid entrance into the housing, and a sampling member 52 positioned in the housing. The sampling member comprises a cavity 53 for receiving and holding a liquid sample (figures 3 and 4) and is "movably positioned as claimed. In the first postion as seen in figures 2-4, the cavity is "in communication with the bore for entrance of the liquid" as claimed. In the second position as illustrated in figures 5-8, the cavity is in communication with a "mixing chamber" 61 allowing for the fluid to be discharged as seen in figure 6. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Berndtsson with those of Hanss and Graham to allow for a blood sample to enter the system directly from a donor such as the one seen

in figures 3 and 4, denoted by the reference character F. This allows for faster, on site testing without the need for external syringes or pumps.

Regarding **claim 40**, while Graham does not explicitly disclose using the volume meter to determine a period during which a fixed volume passes through the orifice, the volumeter is capable of measuring the volume passing through and thus would be capable of determining a period between a no volume passing through and a any desired amount passing through.

Regarding **claim 41**, Hanss discloses an apparatus for the measurement of red blood cell deformity comprising two separate chambers 2a, 2b forming a housing, each comprising a cavity 11, 12. Cavity 11 (collection chamber) is separated by cavity 12 (mixing chamber) by a membrane 5 made of plastic material or polymer (column 2 line 37). The membrane contains an “orifice" in the pores which allow particles to pass through from one cavity to the other (column 2 line 38).

The interior of the conduit of Graham is described as being hydrodynamically smooth and further describes a diameter of conduits used to be within a range of 10μm to 2000μm, or 30μm to 200μm for other applications (column 3 line 15). It would have been obvious to one of ordinary skill in the art at the time of invention to use the same sized orifices of Graham with the membrane of Hanss depending on the size of the particles passing through or if the cells under test were larger than those normally found in a human. Graham further describes the conduit 10 as a volumeter which measures the volume of liquid passing through.

Regarding **claim 42**, while Graham does not explicitly disclose using the volume meter to determine a period during which a fixed volume passes through the orifice, the volumeter is capable of measuring the volume passing through and thus would be capable of determining a period between a no volume passing through and a any desired amount passing through.

**Claim 30** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanss in view of Graham as applied to claim 22 above in further view of Berndtsson International Publicaiton WO 99101742 (hereinafter referred to as Berndtsson).

Regarding **claim** 30, Hanss in view of Graham discloses the claimed invention with the exception of the bore in the outer surface of the housing and the sampling member. Berndtsson discloses a disposable sampling device for particle counting apparatus comprising a housing with a bore in the outer surface 55 (figure 2, page 5 line 29) allowing for liquid entrance into the housing, and a sampling member 52 positioned in the housing. The sampling member comprises a cavity 53 for receiving and holding a liquid sample (figures 3 and 4) and is "movably positioned as claimed. In the first postion as seen in figures 2-4, the cavity is “in communication with the bore for entrance of the liquid” as claimed. In the second position as illustrated in figures 5-8, the cavity is in communication with a “mixing chamber” 61 allowing for the fluid to be discharged as seen in figure 6. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Berndtsson with those of Hanss and Graham to allow for a blood sample to enter the system directly from a donor such as the one seen

in figures 3 and 4, denoted by the reference character F. This allows for faster, on site testing without the need for external syringes or pumps.

***Response to Arguments***

Applicant's arguments filed 18 June 2009 have been fully considered but they are not persuasive.

Applicant argues on page 11 of the remarks that the Hanss reference is used for measuring transit times of red corpuscles through a pore and that the reference fails to teach a volume meter as claimed. Examiner contends that the structure taught by Hanss in view of Graham reads on the claimed invention and therefore the means in which it operates or performs a desired function is not relevant. In addition, the Graham reference is not relied upon to teach the membrane, but rather the size and shape of the pores which are in fact formed within an element 51 which is described as a polymer in the specification. As the Graham reference is not relied upon for teachings of the membrane, it would have been obvious to combine the references as previously stated. With regard to the arguments of claim 29, there are no teachings in the prior art as to why the apparatus must be reused and thus, the cartridge is fully capable of being for "single-use" as claimed. Further, the limitations of making something single-use does not change the claimed structure in any way and therefore is not seen as adding additional limitations to the apparatus. With regard to claim 30, as previously stated, the limitations relating to the membrane are found in the original Hanss reference and not the secondary references.

New claims 33-41 are discussed in detail above as they comprise subject matter previously presented in addition to limitations discussed in the present rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK SHABMAN whose telephone number is (571)270-3263. The examiner can normally be reached on M-F 8:00am - 4:30pm, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. S./
Examiner, Art Unit 2856

/Hezron Williams/
Supervisory Patent Examiner, Art Unit 2856